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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,051	02/25/2002	Jurg Gysin	219702US0	9457

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/082,051	Applicant(s) GYSIN ET AL.	
	Examiner David A Saunders, PhD	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-39 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The amendment filed on 12/6/04 has been entered. Claims 30-39 are pending and under examination.

The amendment has overcome all grounds of rejection stated in the action of 7/6/04.

New grounds of rejection follow:

Claims 30-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 30 recites new matter.

The examiner first notes that every feature of claim 30 is disclosed. That is, lines 1-6 are recited in original claim 1. The two hybridomas recited at lines 8 and 11 are recited in original claims 21-22 and 24-25.

The examiner secondly notes that these originally disclosed features have been combined in a way to recite a method that was not originally disclosed. Specifically the examiner notes that claim 30 is now limited to either of two embodiments "selecting a hybridoma which secretes an antibody having the same epitope specificity as the antibody produced by hybridoma PF26G1/B4 (in embodiment 1)... or ... by hybridoma PF26G1/C10" (in embodiment 2). To one of skill, it would be recognized that such a selection process would require that one use either the B4 or the C10 secreted antibody as a "gold standard" for defining the epitope. One would then typically conduct a competitive binding immunoassay in which either the B4 or C10 "standard" antibody and

Art Unit: 1644

the one from the hybridoma being selected are reacted with antigen containing the epitope of B4 or C10, in order to determine if the "standard" antibody and the one being selected can cross-compete for binding to the antigen.

The examiner finds no such selecting step, for a hybridoma disclosed, however. Example two simply discloses that the B4 and C10 hybridomas were selected for their secretion of an antibody which binds to some epitope on plasmodium [^]falciparum infected cells. There was no disclosure that these epitopes were of such particular interest that one would then employ the B4 and C10 antibodies as "gold standards" for screening for other monoclonal antibodies the bind to (e.g. cross-compete) these epitopes.

Applicant is referred to Harlow et al for assay methods used to determine whether two monoclonal antibodies bind to the same epitope.

Claims 30-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant must assure public accession to the two hybridomas recited in claim 30, in order to enable the practice of the method.

As noted supra, in the new matter rejection, the claims are recited such that the antibodies produced by the two recited hybridomas are the "gold standards" against which one compares the binding specificity of any antibody from a hybridoma being selected. Whether one conducts a competitive binding assay or some other kind of

Art Unit: 1644

immunoassay, one practicing the method claimed would need to have each of the antibodies secreted by the recited hybridomas in order to define the binding specificity of any antigen preparation used in a selecting process. Public assurance must therefore be assured. The collective requirements of 37 CFR 1.801-1.809 must be met.

Claims 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As noted supra, under the 112, new matter rejection, the examiner considers claim 30 to be recited in such a manner that one of skill would recognize that each secreted antibody, B4 or C10, is being used as a "gold standard" for defining an epitope, against which one is screening for antibodies which bind to one of these same epitopes.

Since the B4 or C10 antibody is being used as such a "gold standard" reagent in the selecting process, the examiner is baffled by claims 36-37. If "the antibody" at line 1 of each refers to "a monoclonal antibody" of claim 30, line 1, then one is conducting a method which uses one of the "gold standard" antibodies to select the same "gold standard." If "the antibody" at line 1 of each of claims 36-37 refers to "an antibody" at lines 7 or 10 of claim 30, then claim 36 is no different from claim 31, and claim 37 is no different from claim 32; in such case claims 36-37 would be substantial duplicates of claims 31-32. See 37 CFR 1.75 and MPEP 706.03 (k).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1644

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Application/Control Number: 10/082,051


Page 6

Art Unit: 1644

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

March 7, 2005



DAVID SAUNDERS
PRIMARY EXAMINER

ART UNIT ~~182~~ 1644